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jc845 U.S. PTO 08/22/00

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	16693-2
First Inventor or Application Identifier	K.P. Pathak
Title	RENEW COMPRESSION SCREW
Express Mail Label No.	EM485878279US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)*
(Submit an original and a duplicate for fee processing)

2. [X] Specification [Total Pages 18]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 6]

4. Oath or Declaration [Total Pages 24]
a. [X] Newly executed (original or copy)
b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
i. [ ] DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

** NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).*

5. [ ] Microfiche Computer Program *(Appendix)*

6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. [ ] Computer Readable Copy
b. [ ] Paper Copy (identical to computer copy)
c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [X] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*
[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: _____/_____
Prior application information: Examiner _____ *Group / Art Unit:* _____
For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [X] *Correspondence address below*

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Signature		Date	08/22/2000

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PTO/SB/09 (12-97)
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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR	Docket Number (Optional) 16693-2

Applicant, Patentee, or Identifier: Kartikeya P. Pathak

Application or Patent No.: _____

Filed or Issued: _____

Title: RENEW COMPRESSION SCREW

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- [X] the specification filed herewith with title as listed above.
- [ ] the application identified above.
- [ ] the patent identified above.

I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- [X] No such person, concern, or organization exists.
- [ ] Each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

Kartikeya P. Pathak		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Pathak .		
Signature of inventor	Signature of inventor	Signature of inventor
7.24.2000		
Date	Date	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	)	BOX
	)	PATENT APPLICATION
Kartikeya P. Pathak	)	
	)	
Serial No.	)	
	)	
Filed August 22, 2000	)	
	)	
RENEW COMPRESSION SCREW	)	August 22, 2000

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Commissioner for Patents
Washington, DC 20231

Sir:

As a Preliminary Amendment to the above-referenced Application, please enter the following amendments prior to computing the filing fees therefore.

IN THE SPECIFICATION

On page 7, between lines 8 and 9, please insert --SUMMARY OF THE INVENTION--.

On page 8, line 8, please delete "BRIEF SUMMARY OF THE INVENTION."

Express Mail Label No. EM485878279US **Date of Deposit: August 22, 2000**

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, DC 20231.

Sheryl L Hutchings
Signature of person mailing paper or fee

IN THE CLAIMS

Please delete claims 1-8, and insert in lieu thereof new claims 9 and 10 as follows.

9. An external fixator bone implant, comprising, a rod-like device having a first end and a second end, a thread at said first end, an intercalated screw-head between said thread and said second end, and means for providing a grip on said driver at said second end.

10. The device of claim 9, and further comprising a cannulated tip between said thread and said first end.

Respectfully submitted,

By: _____

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TITLE OF INVENTION

Applicant:- Dr. Kartikeya Pranjivan Pathak

Citizen of India

Resident at- 260/5, "Harinav",

Navrangpura, Near Panjabi Hall,

Ahmedabad- 380009, India.

"The Renew Compression Screw", a basic bone implant device for external fixator with improved and renewable stability, also serving as a lag screw with renewable compression, creating improved and durable bio-mechanical conditions for bone union.

CROSS- REFERENCE TO RELATED APPLICATIONS

" Not Applicable"

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

" Not Applicable "

REFERENCE TO A MICROFICHE APPENDIX

" Not Applicable "

BACKGROUND OF THE INVENTION

This relates to the field of Orthopedics and Trauma, human, or veterinary. It may also have applications in non-living mechanical materials.

Bone is living tissue. Bone fragments and surfaces can unite by biological activity over a length of time, given proper conditions to favor it. During this biological process of healing, the fragments have to be held together continuously by various means, to achieve a finally acceptable shape and length of the bone without deformity ,and of sufficient strength to restore function to the part.

The biological process is favored by the following measures.

- Immobilization of the fragments or surfaces attempting union.
- Compression of the surfaces to increase the rigidity of immobilization, and also promoting the biological process of direct union without excessive callus formation.
- To relieve stress and recurrent injury to the soft-tissues and neuro-circulatory mechanisms by the immobilization.
- Immobilizing only the healing parts, and to encourage movement and activity of un-injured parts.

This has been attempted by the following methods.

A. Continuous traction.

B. External casts of Plaster of Paris, other casting material and braces.

C. Internal fixation.

D. External fixation.

E. Combined methods of fixation.

F. This refers to the properties of the claimed invention.

A. Continuous traction:-

This can restore the length of the limb, and further measures can correct deformities like rotation and angulation to some extent.

The following problems of this method seldom make it the preferred treatment.

- It is difficult to maintain the traction force continuously even with very frequent attention.
- Patient cooperation is difficult to achieve.
- Due to intermittent loss of traction force, mal-union may occur. Distraction and movement of fragments may cause delay or failure of union.
- Circulatory problems can occur in the distal limb.
- Wounds in the traction surface will not allow such a treatment.

B. External casts of Plaster of Paris, other casting material and braces.

The following problems are associated with them.

- The immobilization is not rigid enough when it is critically essential.
- Encircling of the part causes sweating and discomfort in hot climates.

- Pressure sores can occur at pressure points, or due to insertion of hard objects by patient for scratching. Bugs can get in.
- Swelling of part within the cast can cause tightness and loss of circulation.
- Loosening of cast occurs due to loss of swelling of part, or due to moisture reducing the thickness of the padding, resulting in loss of reduction.
- There is no access to any wounds inside which may need attention, except by cutting out windows or leaving the cast incomplete, which may jeopardize the immobilization, and fracture reduction.
- Uninvolved parts also get immobilized, a setback to recovery.

Due to these factors it can suffice only when rigid immobilization is not critically important, and usually in the absence of complicating factors of wounds and circulation.

C. Internal fixation :-

This may be applied along the side of a bone in the form of a plate and screws of the preferred design. It allows accurate reduction when this is most desirable, a bone graft can be added, and lag screws may be added when feasible, for inter-fragmentary compression. Sliding devices can be added to passively close any gaps arising later.

Disadvantages are as under.

- Large exposures are required with relatively greater damage to the soft-tissues and bone circulation. Meticulous technique may minimize this, yet exposure is larger.
- Compression once applied at operation, wears off within hours depending on the quality of bone. There is no possibility of renewing this compression once the wound is

closed over the device. It is not acceptable to re-anaesthetize and re-expose the device repeatedly to re- tighten the screws.

- Newer minimally invasive methods are performed through smaller incisions but in order to place the plate directly on bone, the periostium and muscles have to be stripped blindly. Even so, the plate is always unavoidably placed over some soft-tissues which melt away by the pressure and loosen the plate within hours. Loss of torque of screws is unfavorable to bone biology.
- Plates are seldom favored in compound fractures.
- Fracture haematoma gets dispersed.

Internal fixation may be applied inside the medullary canal of bone in the form of nails, pins and wires.

In closed nailings the fracture haematoma is preserved

The disadvantages are as under.

- It is generally not applicable to children, due to growth plates at the ends of bones.
- It invades and occupies the bone from end to end, with the possibility of spreading infection.
- It is not stable to rotational forces, and interlocking methods are not available for all situations.
- In open nailings , the fracture haematoma gets dispersed.

D. External fixation:-

This is most ideally suited for open injuries of bone. The commonly used basic bone implant for the external fixator is the Schanz screw which can be inserted at a safe

distance from the open wounds and fracture ends.

- Access to the wounds for frequent attention is easy.
- There is no aggravation of injury to bone or soft-tissue.
- Safe corridor entries of screws prevent injury to neuro-vascular structures.
- In transverse fracture patterns, some compression can be applied along the axis of the bone

The following limitations remain:-

- The basic implant e.g. the Schanz screw has a tendency to loosen in bone, leading to instability, and tendency to infection. Radial stressing of the implant in bone improves the stability, by the technique of inserting a larger diameter screw in a suitably smaller diameter drill-hole.
- The preload is only in one mode, viz. Radial.
- After loosening, there is no way of regaining any degree of stability in the same position, before the onset of infection. If the loose screw had been initially placed in the ideal site, then any next site for re-positioning the screw will be less than ideal.
- There is no lag screw effect of a Schanz screw, to exert inter-fragmentary compression. Inter-fragment compression greatly enhances the stability, as well as the biological process of union. Fragments can at the most be splinted across, but not drawn together and compressed as in the lag-screw mode, by the conventional Schanz screw.

E. Combined methods of fixation:-

When any one method is inadequate to neutralize all the forces of muscular pull and gravity, another method is added onto the first. For example, in " mini- internal fixation "

methods, one or two lag screws used to hold together some fragments, are supplemented by an external fixator construct, or by traction.

Even with such a supplementation, the lag screws can fail, because by the blind stab-hole technique, there is always some interposition of soft-tissue between the screw-head and the bone surface. This soft tissue quickly undergoes pressure necrosis to loosen the compression by loss of torque. The only residual control then is the external fixator, which may not be adequate for joint fragments. The compression once lost cannot be regained.

E. The claimed invention:-

This invention aims to preserve and augment the function of the primary bone implant of the external fixator. This is by a design which adds the effect of an axial preload on the thread in the bone, to the older technique of radially preloading the implant. This has an additional effect on the stability and durability of the screw. The third element of stability is the surface preload of the screw-head on the bone surface. This is independent of the function of the head in exerting axial preload torque on the thread within the bone. These stabilizing qualities are also renewable, because the screw can be again tightened after the first insertion.

Further, there is the introduction of the "lag-screw" function in the same basic implant of external fixator which is a totally new concept.

There is also the capability of renewed and prolonged inter-fragmentary compression by means of subsequent turning of the screw from outside, which is a new and major advantage to the biology of bone healing.

The major drawback of the conventional Schanz screw of loosening is corrected to a significant extent, by this triple mechanism.

All positive features of the older implant are retained.

This device can be used to supplement minimally invasive plate oesteosysthesis with double advantage. The screw torque can be renewed to keep the plate firmly seated on bone. The same screws form a construct outside and prevent failure of implanted plate.

BRIEF SUMMARY OF THE INVENTION

The general idea and the objective of the claimed invention is to overcome some shortcomings of older methods, and make it more versatile.

The claimed invention combines the beneficial aspects of internal as well as external fixation. The older Schanz screw never had any lag-screw function. Even when used across any fracture line, it would merely splint the fracture but could never compress the fragments. Thus the older screw was mainly for gripping the main fragments for participation in the construct. Lag screw mode was entirely a function of the internally fixed screw, and not the Schanz screw.

As a member of the external fixator class, it has multiple stabilizing factors beyond the present designs; radial preload, axial preload on thread, and surface preload of head on the bone surface. It is designed for increased primary stability and durability and is capable of being re-tightened in the same site, to preserve stability.

It has no disadvantages of any kind whatsoever, compared to the available fixator screw implants, and permits wound access, is applied through minimal incisions, does not

damage soft-tissue as in the open reduction and internal fixation methods, does not invade the medullary canal length-wise, and is applicable to children.

As a member of the internal fixation class of implants, it not only holds but compresses the fragments in the lag- screw mode, and also overcomes the problem of invariable loosening soon after first application. Due to its projection outside the skin, it can be re-tightened as required to renew the compression torque, and simultaneously participate in the external construct to augment stability.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Drawing 1. It shows the essential features of the invention, which is a rod-like implant with the following components.

a. The tip:- This is meant for implantation, and may be self-tapping or not. The device in the drawing is cannulated, to permit a guide-wire technique. However, it may be solid in other samples of the device.

b. The thread:- The drawing shows a partly threaded device, which is intended for use as a lag screw. When intended as a basic implant, or when not intended for compression, the thread extends to the screw- head.

c. The smooth shaft of screw section:- This is absent in a fully threaded device. The distance between the partial thread and the head is variable to suit the length of the sliding drill-hole.

d. The screw head:- This is may be shaped hemispherical like the conventional screw – head, discoid, reverse conical, spherical or any other shape so

long as it can rest on the bone surface and be driven tight against it. It may be integrated

into the implant body or may be loosely or separately fitted.

e. The external drive-shaft:- This extends from the screw- head to the exterior end of the device, and may be of any suitable diameter.

f. The grip:- This outer end of the device may be identical with the rod. It may be milled, or flattened to an isosceles triangle for gripping, or a quick-coupling type.

All the dimensions are variable; the diameters of the canulation, the outer thread, the core, the screw-head, the external rod; as also the lengths of the thread, the tip to head distance, and the overall length.

Drawing 2.

A. This shows the conventional radial preload, by driving a screw into a smaller diameter drill-hole. The view is a cross- section.

B. This shows the axial preload on the thread along the axis of the claimed invention, upon the thread in the bone. The implant is axially tensioned. There is radial preload also.

C. This shows the surface preload of the screw- head upon the surface of the bone, independent of the axial preload. The fixed flat under – surface is of a limited contact type and used at right angles to bone surface. At any other angle, the under surface is spherical, a washer may be added on a thin cortex. There is also radial preload.

Drawing 3. This shows a common variety of hip fracture, treated by internal fixation with a frequently used two- piece device. At the end of fixation, compression is applied between the fracture surfaces, with another smaller fine threaded screw, which draws the hip-screw into the plate barrel. After the wound is closed over the device, the compression wears off. Any subsequent gap due to bone resorption may get closed by

sliding of the screw within the barrel. If this passive movement fails to occur, the persistent gap causes failure of union and implant.

Drawing 4. The same fracture is treated with an external fixator. The fragments are splinted over the upper two Schanz screws, but no active compression is present. Passive sliding cannot occur, unless the screws are loose in the clamps, making the construct unstable. The lower two screws are the basic implants of the fixator, which can exert preload only in the radial direction, if driven in suitably smaller drill-holes. There is no element in the design for the addition of other preload factors, or for renewability of preloads. Axial preload is not renewable.

Drawing 5. The claimed invention is used to create an external fixation construct. The upper two screws actively compress the fracture surfaces by the lag-screw effect. The same screws simultaneously participate in the external construct. Any subsequent loosening can be overcome by re-tightening the lag-screws to regain the compression.

The lower two screws are the basic implants for completion of the construct. In addition to a radial preload by technique, the head exerts surface preload on the bone by implant design, adding to the lateral stability. In addition, there is an axial preload along the screw thread on tightening the screw. The latter two effects are incorporated in the design of the invention, and are renewable by re - tightening from without. Axial preload is not renewable but it is protected by the two newer forces.

Drawing 6. The claimed device plays an invaluable role in the management of an intra-articular fracture. The articular fragments are not only splinted but actively

compressed by the claimed invention. This compression by the lag-screw principle is also renewable. The same device is incorporated in the external construct, to hold the articular fragments reduced to the rest of the bone. The articular screws need not be in the same plane as shown in the drawing, and can be creatively inter-connected to other construct components.

DETAILED DESCRIPTION OF THE INVENTION

The invention distinguishes itself from older internal fixation screws in lag mode by the following qualities.

The conventional lag screw is imbedded in the tissues after the wound is closed over it, whereas the invention projects outside the skin surface.

The conventional screw in lag-screw mode cannot be accessed repeatedly for refreshing the compression between fragments. This would require repeated anaesthesia and reopening of the wound. The invention being outside the skin can be loosened in the clamp, turned tighter on the bone, and secured again to the clamp.

The invention distinguishes itself from the conventional basic implant of the external fixator in the following features.

The conventional implant can be inserted with a radial preload to enhance its stability, by driving it through a suitably smaller drill-hole. The radial preload can be applied in this invention also. However, in addition to this radial preload, the principle incorporated in its design adds two other stabilizing factors. One is an axial preload along the thread. The other is the surface preload of the head on the bone surface, which works at an angle of 90 degrees to the radial preload. These three combined effects gives the

invention better immediate and more durable stability without loosening.

The conventional Schanz screw implant once loosened, stays loose and encourages sepsis. Due to the presence of the intercalated head in the invention, it is possible to renew its stability by turning it tighter, periodically. Stability of implant discourages sepsis. Though the radial preload is not renewable, when supplemented by the other two preloads, it lasts longer. Even if radial preload is abolished with time, the other two are renewable.

The conventional Schanz screw was never intended for the lag-screw mode. It was primarily for getting control over the main two fragments of bone in a fracture by engaging them. After this the fragments could be manipulated into reduction by moving the fragments about with the leverage gained, and fixed. If ever inserted across a fracture line, it could only splint the fragments across, with or without gap. Passive sliding is prevented by the fixator clamps.

The claimed invention is not only capable of being inserted in the lag-screw mode, but has the unique quality of allowing renewal of the compression from out-side. This is in addition to its function as a basic implant.

The tip of the screw is self-tapping where the torque required is not excessive. In hard bone , more lasting stability is gained by using a bone-tap prior to screw insertion. Short threaded screws in lag mode, and those which may need removal and replacement, are not self-tapping.

The cannulated pattern can be very helpful for intra-articular fragments, by allowing a guide-wire technique.

The length of the thread is short when intended for the lag-screw mode. The thread can then be kept out of the fracture line at the end of tightening.

For the basic implant mode, the screw is fully threaded, to encourage broader contact area for axial preload on the thread.

For fixation of intra-articular comminution, a fully threaded screw is chosen to prevent the articular surface from getting narrowed.

The ratio between the outer diameter of the screw and the core diameter is generally larger in cancellous bone than in cortical bone. The pitch of the thread is higher for cortical bone.

If the partially threaded device is used, the smooth screw-shaft is of sufficient length and proper diameter to clear the gliding hole in the near fragment.

If intended as a renewable compression lag-screw, the thread length selected will be such that the thread does not cross the fracture line, at the end of tightening.

The presence of a shaft from the thread to the head is only for gliding of the screw in the near fragment; for compression without catching in that fragment, in the lag-screw mode. Radial preload is still applicable.

The most functional part of the invention is the intercalated screw-head, its shape and position, which adds to the meaning and alters the functions of other components of the device.

The head, which is intercalated between the inner and outer tips of the device may be fixed to the rod , or may be mobile. It may be hemispherical on the deeper side like a conventional screw-head, spherical, or discoid or any other shape that may suit its

purpose of exerting the intended pressure on the bone surface. The discoid head may have a blunt serrated deeper surface to exert limited contact. There may be an in-built washer under the head, which distributes pressure over a wider area over bone surface.

The external drive-shaft is an extension of the inner screw, to give it the simultaneous functions of participation in an external construct, and of renewing the compression torque.

The outer grip end can be, by the preference of the user, either milled or quick coupling or triangulated.

The overall size of the device can be made to suit the size of the bone, the size of fragments being dealt with, and the depth of the bone from skin.

The device being an implant shall be manufactured out of an inert implantable material, having other suitable physical attributes.

CLAIMS

What I claim as my invention is:-

An implantable screw-like device which can serve simultaneously the following Functions or capabilities.

1. Acting as an improved basic external fixator implant with triple stabilizing factors of radial preload around the drill-hole of a smaller diameter, axial preload on the thread along the length of the drill-hole, and surface preload of the head upon the bone surface at 90° to the radial preload.

2. Capable of renewing the enhanced stability by subsequent turning of the device.

3. Acting simultaneously in an internal lag-screw mode, and participating in an external fixator construct.

4. Capable of repeated renewable lag-screw compression from outside the skin, since this compression always gets loosened with time in the conventional implanted lag-screw, without any need for repeat anaesthesias or re-exposures to search for screw-heads.

5. Adding the renewability of compression, to cannulated screws in lag mode, inserted with guide-wire technique into joint fragments.

6. The claim is for the principles stated above and not for any single particular pattern or dimensions thereof. I claim any device capable of the above functions, made of whatever material, whether for human or veterinary or any other implantation or mechanical application, as my invention.

7. While originally being intended for the above purposes, I further claim the

invention even if it is used for other biological fixations/ immobilizations such as botanical or other forms of life, and in tissues other than bone wherever applicable.

8. I further claim this invention in connection with any other use as in engineering or any other field of mechanical or biological endeavor, in which it serves to hold and compress together two or more fragments or masses of material together, while taking part in an outside construct.

ABSTRACT OF THE DISCLOSURE

The claimed invention called the "Renew Compression Screw" pertains to a rod-like screw device with a thread at the deep end, an intercalated screw-head between the thread and its outer end for participation in a construct, primarily intended for use as an external fixator bone implant. It serves as an improved primary bone implant with triple stabilizing factors instead of only a radial preload. It also serves as a compression screw by lag-screw mode. These two combined functions in themselves are unique, to which is added the capability of renewable stability in basic mode, and renewable compression by lag screw mode. Such a combination of functions has not yet been described in any device.

(K. P. PATHAK)

Place : Ahmedabad, India.

Date : July 16, 2000.

Dr. Kartikeya P. Pathak.

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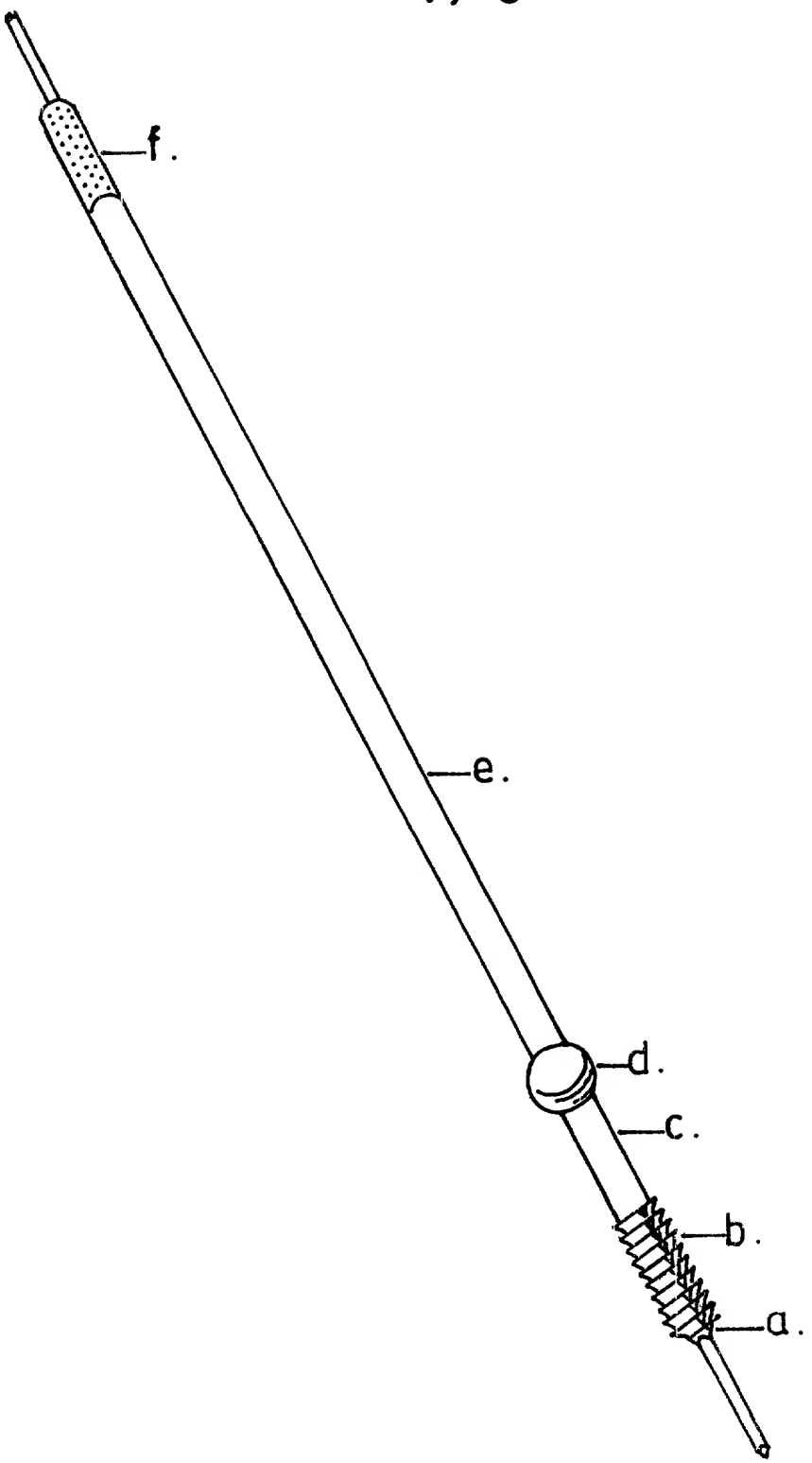
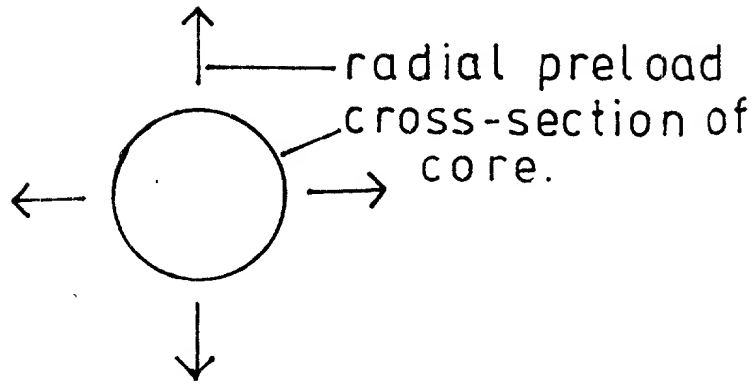


Dr. Kartikeya P. Pathak

A.



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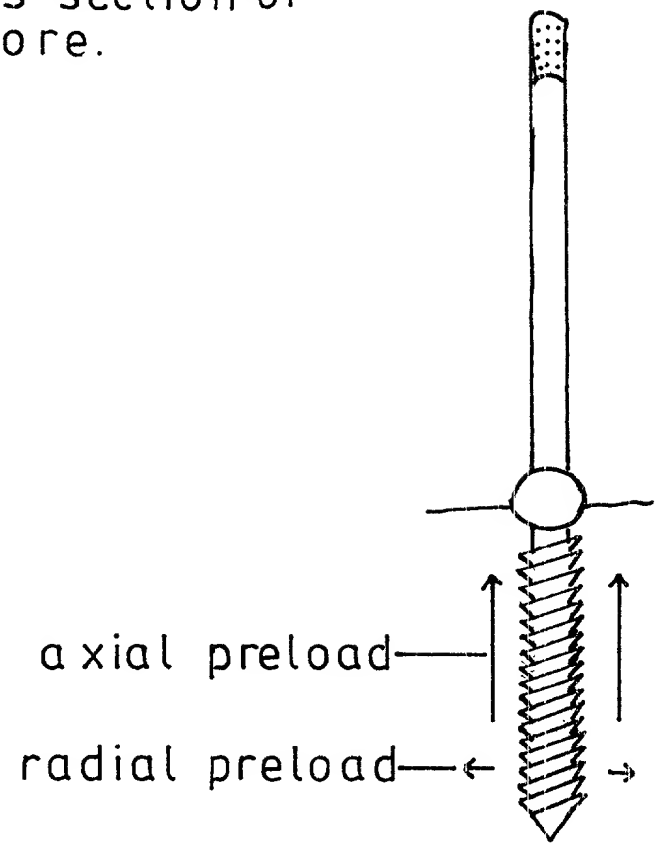
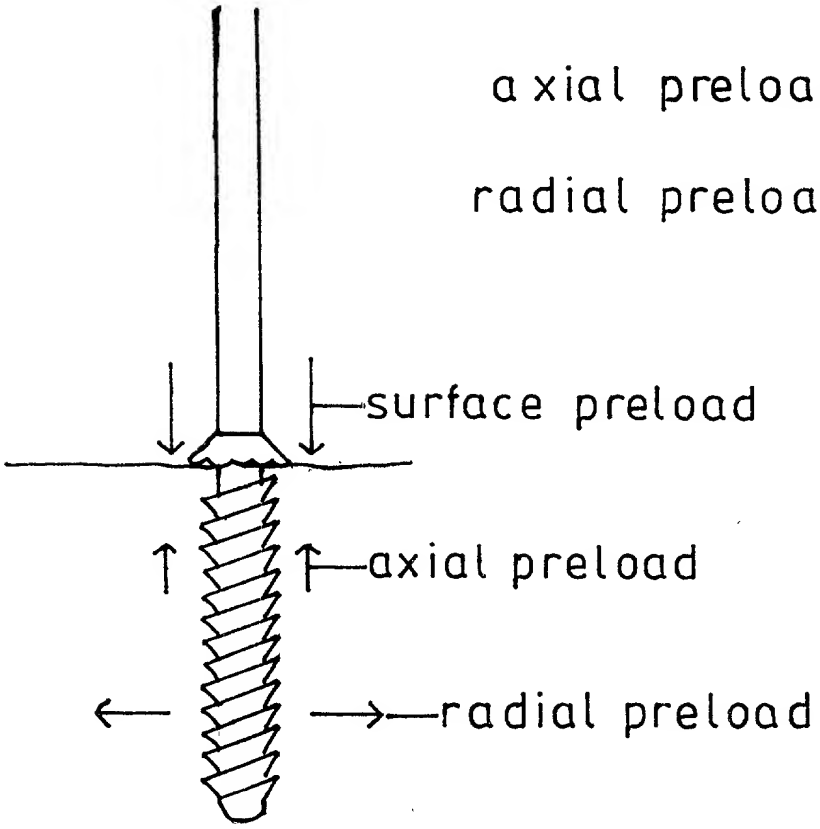


C.



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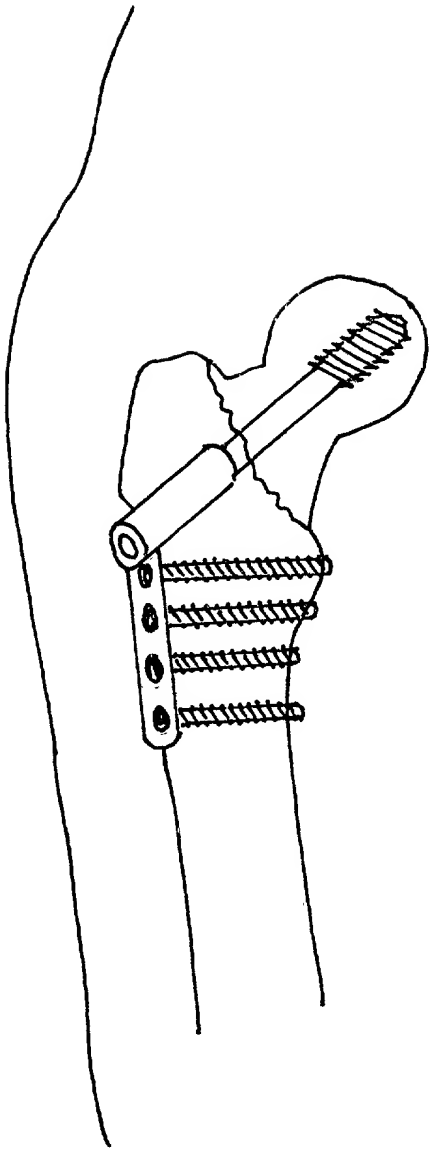

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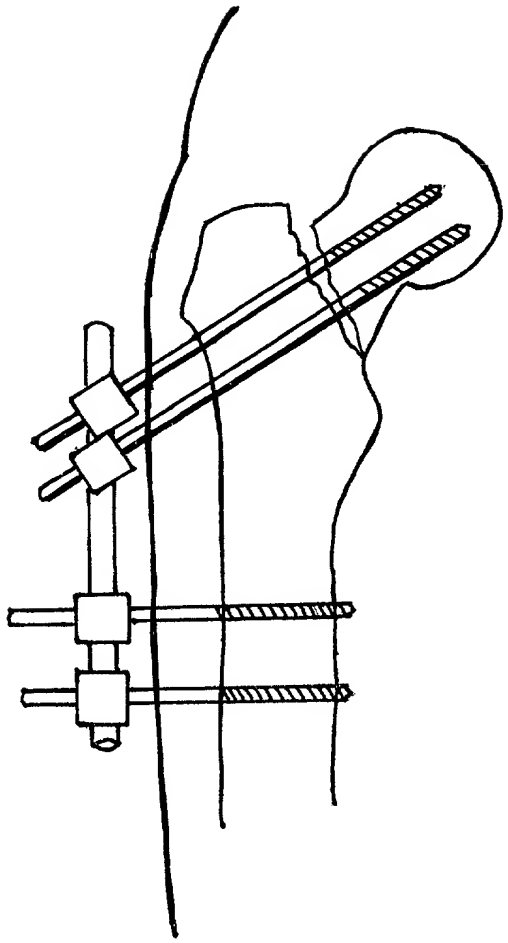

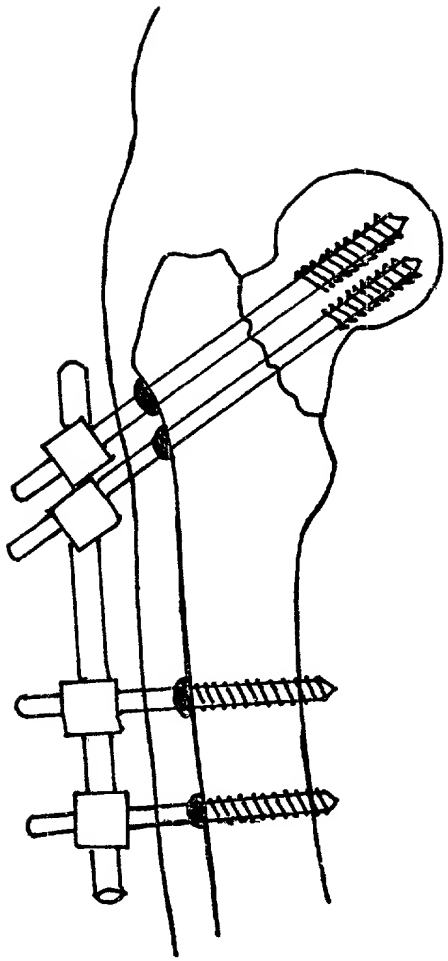

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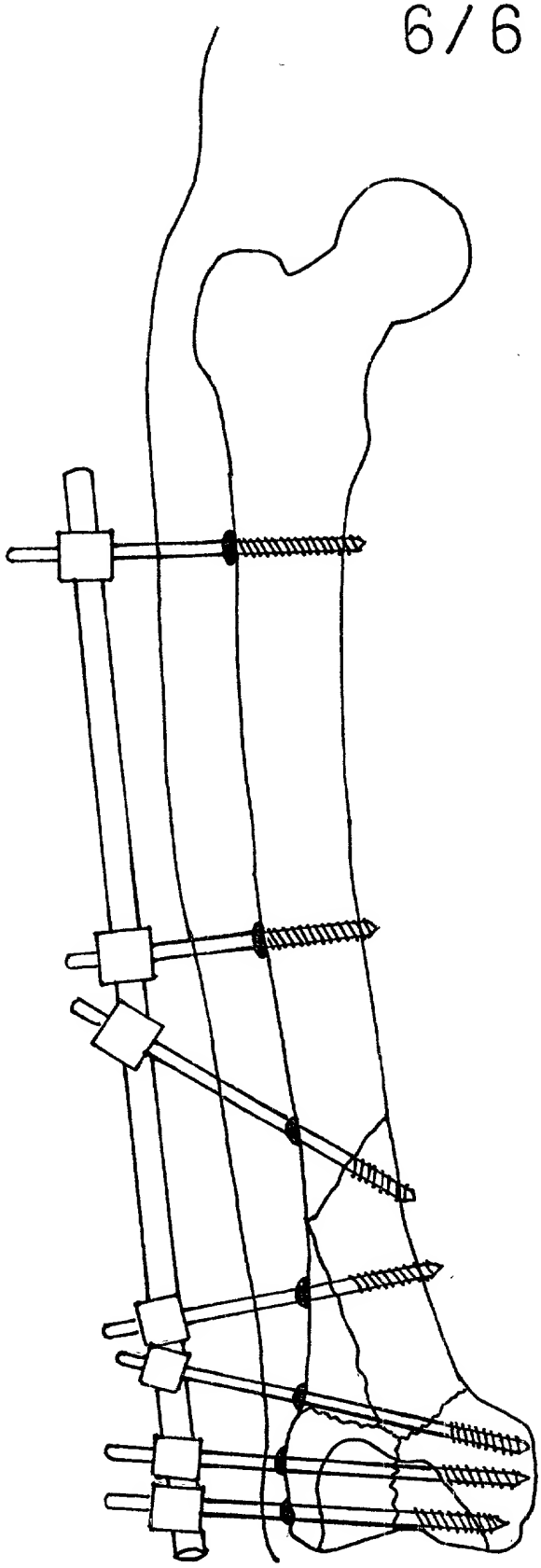

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

[X] Declaration Submitted with Initial Filing OR [ ] Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	16693-2
First Named Inventor	K. P. Pathak
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

RENEW COMPRESSION SCREW

(Title of the Invention)

the specification of which

[X] is attached hereto

OR

[ ] was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
755/BOM/97	India	05/03/1998	[X]	[ ]	[X]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

[ ] Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*

OR

☒ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Clifford W. Browning	32,201		

☒ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] *OR* ☒ Correspondence address below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Kartikeya P.	Pathak

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City		State		ZIP		Country	India

☐ Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto